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EXAMINER	
FOX, DAVID T	
ART UNIT	PAPER NUMBER
1638	36

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/903,944	Smith et al
Examiner	**Group Art Unit**
Fox	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply -3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 5/7/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☑ Claim(s) 1-45, 47-106, 108-118 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-45, 47-106, 108-118 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing R view, PTO-948

☐ Int rview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Acti n Summary

The finality of the Office action of 8 August 2001 has been WITHDRAWN in view of the following new grounds of rejection. The amendment of 9 November 2001 has been entered, and has obviated the errors and outstanding rejections of the claims under 35 USC 112, second paragraph, outlined on pages 2-3 of the Office action of 8 August 2001. The amendment of 15 October 2001 remains non-entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-45, 47-72, 80, 102-103, 105-111 and 113-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claims 1, 6, 102 and 103 are indefinite in their recitation of "comprising casein hydrolysate and NH4+ and/or NO3-" as it is unclear whether casein hydrolysate is required, in combination with either NH4+ or NO3-; or whether only casein hydrolyaste, NH4+ or NO3- is singly required. If the former were intended, the following amendment would obviate this rejection:

In claims 1, 6, 102 and 103, part (b), insert --further comprising-- before "NH4+".

Claim 6(c)(ii), 39(h)(ii), 102(c)(ii), and 103(h)(ii) are indefinite in their recitation of "by microprojectile-mediated delivery of the vector into" as it is unclear whether only one vector is introduced by microprojectile-mediated delivery, or whether more than one vector (as recited

earlier in the claim as "Agrobacterium tumefaciens containing the vector or vectors") is intended to be inserted via microprojectile bombardment. If the latter were intended, amendment of the claims to insert --or vectors-- after "vector" would obviate this rejection.

Claim 80 is indefinite in its recitation of "said second foreign gene" which lacks antecedent basis in claim 76 from which it depends.

Claims 113-118 are indefinite in their recitation of "the nitrogen source" which lacks antecedent basis in the claims from which they depend. Note that amendment of claims 1, 6, 102 and 103 as suggested above would render claims 113, 114, 117 and 118 failing to further limit the claims from which they depend. Currently claims 115 and 116 fail to further limit the claims from which they depend.

Claims 6-37, 39-45, 47-71, 73-96, 98-100, 102-103, 105-106, 108-112, 114-115 and 117-118 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method of producing transgenic poinsettia utilizing particle bombardment of embryogenic callus and the resultant plants produced by such a method, does not reasonably provide enablement for claims broadly drawn to transgenic poinsettia plants produced by any method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only provides guidance for the production of whole, flowering poinsettia plants produced by particle bombardment of embryogenic callus. In contrast, the claims are

broadly drawn to any method of producing transgenic plants including *Agrobacterium*-mediated transformation, electroporation, microinjection, polycation incubation of protoplasts, etc. The claims are also drawn to the production of transgenic plants from any poinsettia variety, and to the production of fertile plants.

The transformation of poinsettia (*Euphorbia pulcherrima*) and obtention of whole transformed plants is unpredictable, as evidenced by Follansbee et al, who were unable to recover whole *Euphorbia* plants following *Agrobacterium rhizogenes*-mediated transformation (see, e.g., page 72A, Abstract). This failure is in sharp contrast to the successful obtention of whole plants from a variety of unrelated species including morning glory, tobacco, alfalfa, potato, rapeseed, cucumber, carrot, poplar, and soybean, following *Agrobacterium rhizogenes*-mediated transformation. See, e.g., Slightom et al, page 3069, Abstract; Sinkar et al, page 688, Abstract and page 695, column 2, top paragraph; Sukhapinda et al, page 209, Abstract; Visser et al, page 594, Abstract; Ooms et al, page 325, Abstract and page 327, Figure 1D; Trulson et al, page 11, Abstract; David et al, page 73, Abstract; Pythoud et al, page 1323, Abstract and second paragraph of column 2, page 1325, column 2, first full paragraph; Rech et al, page 1275, Abstract).

Furthermore, *Agrobacterium tumefaciens*-mediated transformation of poinsettia is unpredictable and unlikely, given the host range limitations of the bacterium and the failure of any workers to report successful transformation of poinsettia via *A. tumefaciens*. Oran teaches that plant extracts of another *Euphorbia* species were toxic to *Agrobacterium tumefaciens* (see, e.g.,

page 297, Table 1 and page 298, Table 2). Caesar et al teach that there are few strains of *Agrobacterium tumefaciens* that successfully infect another *Euphorbia* species, wherein no strains were previously reported to be infective (see, e.g., page 797, column 3, bottom paragraph; page 798, top paragraph of column 1, first full and bottom paragraphs of column 2; page 799, Table 3).

Furthermore, other methods of transformation, such as electroporation and polycation incubation of protoplasts, are dependent upon techniques for whole plant regeneration from protoplasts or single cells, wherein such techniques are not available for poinsettia. Tissue culture techniques which have been developed for poinsettia have traditionally been genotype-dependent (see, e.g., page 15 of the specification, lines 18-26).

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate a multitude of non-exemplified transformation methods and concomitant tissue culture methods for their ability to produce whole, transformed, fertile poinsettia plants of any variety or genotype.

Claims 73-75, 83 and 85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any transgenic poinsettia plant which contains any heterologous coding sequence conferring any trait. No guidance has been provided for a multitude of coding sequences conferring a multitude of traits. Only specific coding sequences

conferring disease or insect resistance, herbicide resistance, modified plant habit, ethylene resistance, antibiotic resistance, early flowering, and delayed senescence were provided (see page 2 of the specification, lines 5-6, 14-15 and 27-36; page 3, lines 12-20; page 5, lines 29-32; page 6, lines 6-9 and 24-26; page 12, lines 17-20; page 28, lines 25-28; page 29, lines 21-22 and 28-29; page 30, lines 31-33; page 38, lines 35-38; page 39, lines 1-2 and 5-6; page 40, lines 3-6, 13-15 and 27-29; page 41, lines 8-11; and claims 76, 78 and 95).

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California* v. *Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the memnbers of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claims 1, 97, 101, 104, 113 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preil et al taken with Lelu et al and DeWald et al, in light of Hartmann et al and Lee et al.

The claims are broadly drawn to a method of regenerating poinsettia comprising inducing epidermal callus on auxin- and cytokinin- containing medium, subculturing the callus on a medium comprising NH4+ or NO3- for the induction of embryogenic callus, culturing the embryogenic callus on a developmental medium comprising an osmotic pressure increasing agent and a cytokinin, cutluring the embryogenic callus on a maturation medium comprising abscisic acid, and recovering poinsettia plants.

Preil (1994) teaches a method for obtaining whole poinsettia plants via somatic embryogenesis, comprising culturing stem segments on a callus induction medium comprising 0.2 mg/L of the cytokinin BAP and 0.2 mg/L of the auxin CPA to form "brownish" callus, followed by subculture to an embryo induction medium comprising 0.1 mg/L of the cytokinin 2iP and a nitrogen source comprising the MS salts which comprise ammonium and nitrate salts, followed by transfer of the embryos to an embryo maturation (or "development") medium comprising 0.05 mg/L of the cytokinin BAP and 3% of the osmotic pressure increasing agent sucrose, followed by subculture to a rooting medium free of cytokinin, wherein whole plants are obtained, wherein suspension culture may be employed, and wherein sieving is employed to recover embryogenic cell clumps and later the embryos themselves (see, e.g., pages 50-53). Preil also teaches that

ABA is beneficial for embryo development and maturation (see, e.g., page 54, paragraph bridging the columns)

Preil et al do not teach the transfer of callus containing the embryos at each step, or the use of abscisic acid in poinsettia somatic embryogenesis.

Lelu et al teach the advantages of abscisic acid for maturation of somatic embryos in larch, alfalfa and soybean (see, e.g., page 117, Abstract; page 118, column 1, top paragraph; page 125, column 2, first full paragraph).

DeWald et al teach the advantages of abscisic acid for maturation of somatic embryos of mango, and also teach the advantages of higher levels of the osmotic-altering agent sucrose (see, e.g., page 837, Abstract; page 839, Table 3).

Hartmann et al teach that MS medium comprises NO3- ions (see page 500, Table 17-1).

Lee et al teach that the callus obtained by the methods of Preil et al was in fact "reddish epidermal callus" (see, e.g., page 182, column 2, first full paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the callus-mediated method of propagating poinsettia as taught by Preil et al, and to modify that method by incorporating abscisic acid for embryo maturation and increased frequency of recovering matured embryos and whole plants as taught by Lelu et al and DeWald et al, given the benefits of this treatment in a wide range of plant species and the expectation that each would have continued to function in its known and expected manner. It would have been further obvious to modify the concentration of the osmotic pressure alterating agent sucrose, as suggested by DeWald et al.

The callus induced by Preil et al was inherently "reddish epidermal callus" as illustrated by Lee et al, and given the recognition by those of ordinary skill in the art that the terms "reddish" and "brownish" are subjective and overlapping. Choice of culturing isolated somatic embryos or embryogenic callus containing said embryos would have been the optimization of process parameters.

Claims 1-3, 97, 101, 104, 113 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preil et al taken with Lelu et al and DeWald et al, in light of Hartmann et al and Lee et al; further in view of Nataraja and Litz.

The claims are broadly drawn to a method of regenerating poinsettia comprising inducing epidermal callus on auxin- and cytokinin- containing medium, subculturing the callus on a medium comprising casein hydrolysate and either NH4+ or NO3- for the induction of embryogenic callus, culturing the embryogenic callus on a developmental medium comprising an osmotic pressure increasing agent and a cytokinin, cutluring the embryogenic callus on a maturation medium comprising abscisic acid, and recovering poinsettia plants.

Preil et al taken with Lelu et al and DeWald et al, in light of Hartmann et al and Lee et al, teach a method for propagating poinsettia via somatic embryogenesis as discussed above, but do not teach the use of casein hydrolysate.

Nataraja teaches the culture of poinsettia zygotic embryos on a medium comprising casein hydrosylate and cytokinin for callus induction, followed by repeated subculture on the medium, wherein embryoids formed which matured into plants (see, e.g., pages 136-137), wherein casein

hydrosylate improves callus formation and subsequent plantlet development in poinsettia (see, e.g., page 136, column 1, bottom paragraph and Table 1; and the rest of the article as stated above).

Litz teaches the use of casein hydrolysate in the embryo induction medium for somatic embryogenesis of another *Euphorbia* species (see, e.g., page 190, Abstract).

It would have been obvious to one of ordinary skill in the art to utilize the callus-mediated method of propagating poinsettia as taught by Preil et al taken with Lelu et al and DeWald et al, in light of Hartmann et al and Lee et al, and to modify that method by incorporating casein hydrolysate as taught by Nataraja and Litz, given the expectation that each would have continued to function in its known and expected manner, as evidenced by the successful use of casein hydrolysate in poinsettia embryo culture by Nataraja and the successful use of casein hydrolysate in somatic embryogenesis of *Euphorbia* by Litz. The callus induced by Preil et al was inherently "reddish epidermal callus" as illustrated by Lee et al, and given the recognition by those of ordinary skill in the art that the terms "reddish" and "brownish" are subjective and overlapping. Choice of culturing isolated somatic embryos or embryogenic callus containing said embryos would have been the optimization of process parameters.

Claims 1-3, 6-8, 11-41, 44-45, 47-106 and 108-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miki et al in view of Preil (1994) taken with Lelu et al and DeWald et al, in light of Hartmann et al and Lee et al, further in view of Nataraja and Litz.

Miki et al teach a particle bombardment technique for plant transformation, wherein a variety of tissues including somatic embryos or embryogenic callus are employed, wherein the technique has the advantage of being widely applicable to a variety of plant species (see, e.g., pages 77-81), and also teach the advantages of introducing a variety of heterologous structural genes and promoters (see, e.g., pages 67-71).

Miki et al do not teach poinsettia transformation, the use of casein hydrosylate, the claimed sequences of media, or suspension culture of poinsettia.

Preil taken with Lelu et al and DeWald et al, in light of Hartmann et al and Lee et al, further in view of Nataraja and Litz; teach a multi-step process for the induction of embryogenic callus from poinsettia stem segments and the recovery of whole plants from the somatic embryos, optionally including a suspension culture step, as stated above. Preil also suggests the incorporation of poinsettia tissue culture into methods for genetic manipulation of the crop (see, e.g., page 49, column 1, top paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the method of particle bombardment of embryogenic callus for crop improvement as taught by Miki et al, and to modify that method by incorporating the poinsettia embryogenic callus produced by Preil taken with Lelu et al and DeWald et al, in light of Hartmann et al and Lee et al, further in view of Nataraja and Litz; as suggested by Preil. The callus initially induced was "reddish epidermal callus" as taught by Lee et al, and given the subjective and overlapping nature of the terms as

discussed above. Choice of culturing isolated somatic embryos or embryogenic callus containing said embryos would have been the optimization of process parameters.

Claims 4, 5, 9, 10, 42 and 43 are deemed free of the prior art, given the failure of the prior art to teach or suggest the use of high concentrations of mannitol for the somatic embryogenesis-mediated propagation of poinsettia.

No claim is allowed.

Applicant's arguments filed 7 May 2002 are deemed moot in view of the new grounds of rejection (and/or newly supplied evidence supporting previous rejections) above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 24, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638